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Toward a construct definition of informed consent comprehension

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Toward a Construct Definition of Informed Consent Comprehension

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ABSTRACT: VARIATION IN HOW INFORMED CONSENT comprehension tests have been developed may be largely due to the absence of a standardized construct definition. Developing a construct definition would provide a standardized framework for determining how an instrument should be constructed, implemented, interpreted, and applied. Therefore, we utilized the Delphi consensus approach with an international expert panel (N = 19) to gather knowledge, opinions and eventually consensus for a construct definition. Expert consensus was achieved after three revision cycles. While acknowledging that there are limitations to this study, it nonetheless should be considered as a step toward standardization of a construct definition of informed consent comprehension.

KEY WORDS: comprehension, informed consent

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SEVERAL STUDIES HAVE EXPLORED the relationship between comprehension and informed consent. Clinical trial participants often report understanding informed consent documents. However, when assessed for comprehension, few can state the purpose of the trial or specific aspects of trial procedures mentioned in the documents (Flory & Emanuel, 2004; Yuval et al., 2000; Daugherty et al., 1995; Lynoe et al., 1991). In response, informed consent comprehension tests been developed to provide the much-needed evidence to make judgments about whether adequate comprehension of informed consent information occurs among potential research participants (Sugarman et al., 2005; Joffe et al., 2001; Miller et al., 1996).

Despite widespread agreement about the need to obtain evidence of comprehension, uncertainty remains about how to establish that evidence. Among the informed consent comprehension tests currently available, there is large variation in how they have been developed, the domain of content which they measure, and how to utilize test results to guide clinical trial decision making. The variation between comprehension tests may be due to the absence of a standardized, agreed-upon definition of the construct of informed consent comprehension. Developing a construct definition can provide a standardized framework for determining how an instrument should be constructed, implemented, interpreted, and applied (Spreitzer & Sonenshen, 2004).

To date, there are no systematic efforts to define the construct of informed consent comprehension. Therefore, our aim was to conduct an international study to establish consensus on a preliminary working definition. This paper proposes a preliminary construct definition of informed consent comprehension. It is anticipated that our proposed definition will stimulate further investigation in order to create a theoretical and conceptual basis for instrument development. The study received ethics approval from the University of Wollongong, Human Research Ethics Committee.

Methods

PARTICIPANTS

A convenience sample of 19 international experts—5 from the United States (US), 7 from Canada (CA), and 7 from Australia (AU)—agreed to take part in our study. The panel was derived from a list of individuals with five or more years of research and/or applied work experience in the discipline of human clinical trial research (n = 11), human research ethics (n = 4), or education/cognition (n = 4). Many of the panelists had extensive experience in two or more of the disciplines listed above.

Phase 1: Preliminary Construct Definition

The first step toward the development of a construct definition was to propose an initial definition to the international expert panel. This definition acted as a baseline from which subsequent definitions emerged. The initial definition was developed by examining the following three commonly debated issues related to measuring

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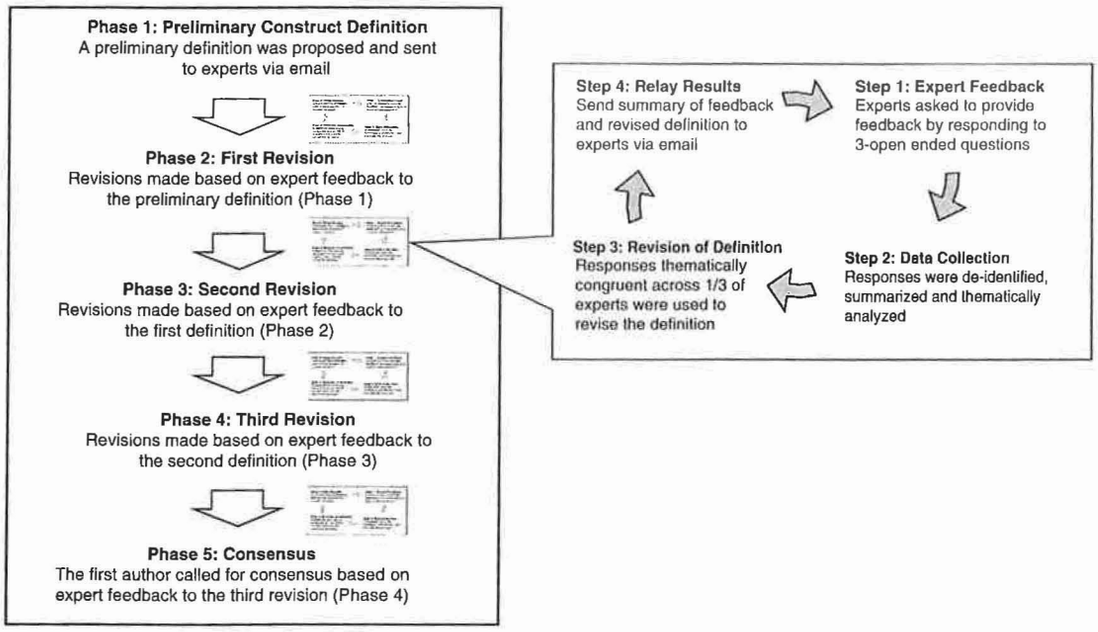

FIG. 1. Methods: Flow Diagram.

informed consent comprehension: (i) What specific consent information should participants comprehend? (ii) What does it mean to comprehend? and (iii) How should it be determined that comprehension of the consent information has occurred? We drew on three primary sources of information to formulate answers to these questions, namely: (i) definitions and ethical requirements established by human research regulatory agencies from the United States (U.S. Food and Drug Administration [FDA], 2001), Australia (National Health & Medical Research Council, 2007 [NHMRC]), and internationally (International Conference on Harmonization–Good Clinical Practice [ICH-GCP], 1996); (ii) lessons learned from previous research studies conducted on informed consent comprehension (Stead et al., 2005; Flory & Emanuel, 2004; Joffe et al., 2001; Yuval et al., 2000; Bogardus, Holmboe, & Jekel, 1999; Bjorn, Rossel, & Holm, 1999; Daugherty et al., 1995); and (iii) the information processing theory of comprehension (Kintsch & Rawson, 2005; Hannon & Daneman, 2001; Alderson & Bachman, 2000; Potts & Peterson, 1985).

Phases 2–5: Revisions Based on Experts' Responses

We used the Delphi consensus approach to gather knowledge, opinions, and eventually consensus for a definition of the construct of informed consent comprehension (Alder & Ziglio, 1996). Experts were asked to respond to the preliminary definition by completing the following open-ended statements: (i) The elements of the proposed definition that I did not like include; (ii) I feel the following elements are essential to keep in the proposed definition; and (iii) My suggestions for modifying or changing the definition are as follows. Expert responses were e-mailed to the first author, who acted as the facilitator of the Delphi consensus process. The facilitator de-identified expert responses in order to maintain experts' anonymity. Responses were then summarized and thematically analyzed. Themes that consistently arose across one-third or more of the experts were used to revise the definition. Experts were given two weeks to respond to each revision. A reminder e-mail was sent to all experts one week before the deadline. This process of collecting, summarizing, and thematically analyzing expert responses was repeated until consensus of a construct definition was reached (see Figure 1). Experts who were unable to provide a response by the indicated deadline were not included in subsequent revisions.

Results

Phase 1: Initial Construct Definition

Using the data gathered from our three primary information sources, we formulated answers to the commonly debated questions (see Table 1). These answers

TABLE 1. Answers to Commonly Debated Questions.

Answers to Commonly Debated Questions	Resources Used
What specific consent information should participants comprehend? The information that should be understood includes the subset of all disclosed information that is most influential to a potential research participant's decision to take part in a research study.	FDA, TGA, GCP, & lessons learned from previous studies
What does it mean to comprehend? Comprehension refers to the integration of previous knowledge with novel information presented within consent documents of which can then be recalled from memory.	Information processing theory of comprehension
How is it determined that comprehension has occurred? Research indicates that a signed consent form alone is not synonymous with comprehension. Therefore, we need to establish methods that extract evidence of compression. According to the information processing theory, comprehension can be extracted by assessing recall of the integrated information (previous knowledge with novel information).	Information processing theory of comprehension & lessons learned from previous studies.

provided a basis for the initial construct definition which was formulated as follows: *Informed consent comprehension takes place once there is evidence that a potential participant has integrated the information determined to be most influential to his or her decision to participate in a study which is confirmed through recall.*

Phase 2: First Revision

All 19 experts responded to the initial definition: 5 from the US, 7 from CA, and 7 from AU (see Table 2: Phase 1). Experts indicated that the terminology "most influential" was too subjective and should be replaced with a more objective standard such as national or international consent regulations. Experts also wanted clarification regarding exactly what information was to be "integrated."

To clarify the concept of "integration," we referred to the information processing theory of comprehension, which states that comprehension is a product of the integration of prior knowledge with novel (new) information (Samuels & Kamil, 1984). Integration of novel information is an important component of comprehension. Instruments that do not attempt to measure understanding of novel information may be measuring a construct other than that of comprehension. For example, many informed consent comprehension tests currently available contain generic question items in order to enhance the usability of the instrument across a variety of trials. Yet, participants who have general knowledge of clinical trials or have previously participated in a clinical trial could correctly complete the comprehension test without truly understanding specific information about the trial to which they intend to enroll. These instruments, therefore, may in fact be measures of general knowledge rather then comprehension. It is the integration of both prior knowledge with novel information that is fundamental to the process of comprehension. Based on the experts' comments and suggestions, the first revised definition was proposed as follows:

> *Informed consent comprehension can be said to occur when there is evidence that a potential participant has integrated novel consent information with his/her current knowledge, which at a minimum, includes the set of information determined by national and international ethics regulations to be most important for potential participants to understand when deciding whether to take part in a research study.*

Phase 3: Second Revision

Sixteen experts (84%) responded to the first revision: 3 from the US, 7 from Canada, and 6 from AU (see Table 2: Phase 2). Twelve of these experts (75%) stated they felt the word "novel" was awkward and suggested that it be removed. It was also suggested that "national and international regulations" was not sufficiently specific and should be changed to "national and international consent requirements." Based on the experts' comments and suggestions, the second revised definition was proposed as follows:

> *Informed consent comprehension can be said to occur when there is evidence, established when the potential participant decides whether or not to take part in the research study, that his/her current knowledge has been integrated with the consent information,*

TABLE 2. **Expert Feedback.**

Congruent Expert Feedback	
PHASE 1: BASED ON PRELIMINARY DEFINITION	**Experts**
Problems with this definition	
The terminology "influential information"	18/19 (95%)
Dislike "through recall" as evidence of understanding–could be obtained through other methods	15/20(75%)
Restructure the definition (wording)	8/19 (42%)
Identify components essential to keep	
The requirement of comprehension	19/19 (100%)
Integration of information	18/19 (95%)
Evidence of comprehension	16/19 (84%)
Suggestions for changes	
Influential information: Change to important, necessary, or salient	17/19 (90%)
Define who determines that this information is most important or influential (i.e., ethics regulations)	13/19 (69%)
Take out "confirmed through recall"	7/19 (37%)
Structure of definition (wording): Change "informed consent comprehension takes place" to "informed consent comprehension can be said to occur"	7/19 (37%)
PHASE 2: BASED ON FIRST REVISION	
Problems with this definition	
The word "novel"	12/16 (75%)
Definition is long and may be confusing	9/16 (56%)
Regulations that are "most important" is ambiguous	9/16 (56%)
Identify components essential to keep	
Evidence	16/16 (100%)
Integration	16/16 (100%)
National and international ethics regulations	15/16 (94%)
Evidence established "at the time when deciding whether or not to take part"	10/16 (60%)
Suggestions for changes	
Take out the word "novel"	12/16 (75%)
Further explain the set of information that participants should understand (i.e., consent requirements)	7/16 (43%)
PHASE 3: BASED ON SECOND REVISION	
Problems with this definition	
Length of definition: too wordy, becomes confusing	12/15 (80%)
Identify components essential to keep	
Evidence	15/15 (100%)
Integration	14/15 (93%)
Who determines: national and international ethics regulations	14/15 (93%)
Definition of when the evidence should be established, i.e., "at the time when deciding whether or not to take part"	12/15 (80%)
Suggestions for changes	
Break the definition down into separate sentences to make it easier to understand	9/15 (60%)
Structure the definition as criteria based using bullets points	6/15 (40%)
PHASE 4: BASED ON THIRD REVISION	
Problems with this definition	14/14 (100%)
None	
Identify components essential to keep	14/14 (100%)
Evidence	14/14 (100%)
Integration	14/14 (100%)
Who determines: national and international ethics regulations	12/14 (86%)
Evidence should be established "at the time when deciding whether or not to take part"	12/14 (86%)
Bullet points	
Suggestions for changes	14/14 (100%)
None	

which at a minimum includes the consent requirements stipulated by national and international ethics regulations.

Phase 4: Third Revision

Fifteen of the previous sixteen experts (94%) responded to the second revision of the definition: 3 from the US, 6 from CA, and 6 from AU (see Table 2: Phase 3). Overall, the experts stated that they were satisfied with the content of the definition. However, there was consistent feedback pertaining to the length and structure of the definition. Suggestions were provided on how to break down the definition by using bullet points. Based on the experts' comments and suggestions, the third revised definition was proposed as follows:

Informed consent comprehension can be said to occur when the following conditions are met:

- *There is evidence that a potential participant has integrated his/her current knowledge with the consent information;*
- *The evidence occurs at the time the potential participant decides whether or not to take part in the research study;*
- *At a minimum, the integrated consent information includes the consent requirements stipulated by national and international ethics regulations.*

Phase 5: Call for Consensus

Fourteen of the fifteen experts responded to the third revision of the definition: 3 from the US, 6 from CA, and 5 from AU (see Table 2: Phase 4). Experts continued to express satisfaction with the content and structural changes. With no new suggestions for revisions, the first author of this study called for consensus on the third revision of the construct definition. All 14 experts approved the third revision.

Discussion

The importance of developing a standardized definition of any construct, such as informed consent comprehension, cannot be overstated as the validity of what is being measured will rest largely on the definition. Instruments developed in the absence of such a definition are likely to lack construct and/or content validity which, in turn, would result in the appropriateness of the instrument being challenged (Schwartz, Patrick, & Yueh, 2001). As well, standardization allows for comparison of results across research and enhances generalizability of findings (Netemeyer, Bearden, & Sharma, 2003). Developing a standard method of communicating about informed consent comprehension could have a significant impact on how comprehension is measured and how subsequent instruments are developed.

Our study began with a convenience sample of 19 experts. Five experts did not respond by the predefined deadlines and therefore were categorized as dropouts. We did not seek explanation from non-respondents regarding why they did not comment on the definition. Although our study included international representation, the number of experts was relatively small and represented only three countries that are culturally similar. To account for these study limitations, further development of the construct definition should involve a larger global panel of experts from more culturally diverse countries. This process could greatly enhance the strength and generalizability of the definition.

The Delphi approach provided a systematic method for establishing consensus on a preliminary definition (Alder & Ziglio, 1996). However, this approach is limited in that it does not provide an avenue for stimulating in-depth discussion or debate nor does it require experts to provide justification for their responses to the open-ended statements. Modifications to the definition were therefore based on the level of agreement between the experts. Feedback that was not thematically similar across one-third or more of the expert panel was not used in the construct revisions. Therefore, significant input may have been dismissed because it did not meet our predefined cut-offs. In order to develop a strong argument that supports the construct definition, additional studies should employ methods that require the experts to justify their suggestions to modify the definition.

Research Agenda

With the growing legal and ethical concerns about informed consent, more rigorous research in this area is warranted. While acknowledging that there are several study limitations, this study should be considered as an initial step toward standardization of a construct definition of informed consent comprehension. It is our hope that this proposed definition will stimulate further investigation and theoretical development to enhance understanding of the construct and hence help guide the development of informed consent comprehension instruments.

We suggest a major international face-to-face forum as an appropriate next step. The forum should include a reasonable number of experts from diverse geographic and cultural backgrounds. The panel should also be

representative of a variety of disciplines, such as those involved in human research, research ethics, cognitive sciences, and law. The immediate focus of the discussions would be further refinement of the preliminary construct definition of informed consent comprehension. Other issues that should be addressed during the forum include: (i) Are current national and international regulations appropriate as they stand or do they need to be revised? (ii) Which research participants should be required to undergo a comprehension evaluation? (iii) How much comprehension should be required? This platform would encourage those who are responsible for the ethical conduct of research to engage in dialogue about how these and other related issues might be approached in their own countries and in international collaborative research.

In its current state, our proposed definition includes the requirement that potential participants understand information stipulated by national and international consent requirements. A number of the consent requirements that exist within and between countries can vary greatly in content. This is an important issue for multi-center, international trials where it may not be practical for participants to comprehend each country's separate requirements. Perhaps it would be possible to establish a standardized, core set of consent requirements that are applicable within and across countries. Discussion is also needed regarding whether the various consent requirements, as they stand, represent what they were intended to represent or whether they in fact need to be revised.

Other immediate issues relate to whether all research participants should be evaluated for comprehension and what type of evaluations should be utilized. Such decisions will most likely be based on the level of risk presented in a study. For example, should informed consent comprehension be assessed only for greater-than-minimal-risk research and if so, is there a universal, agreed-upon definition for greater-than-minimal-risk studies? Should the amount of evidence of comprehension that is required directly correspond to the level of risk involved with a study? Should evaluations be oral or written, criterion-based or norm-referenced? Answers to these questions are very important, primarily because they inform test developers about the type of test items that should be included within a comprehension test. They also inform clinical trial researchers of when comprehension should be assessed and how much comprehension is enough to conclude that consent to participate is truly informed.

Although a few instruments have been developed to measure informed consent comprehension, they have been developed in the absence of a construct definition (Sugarman et al, 2005; Joffe et al., 2001; Miller et al., 1996). To our knowledge, this is the first standardized proposed definition. This research should therefore be viewed as a preliminary study; additional research is required to improve the proposed definition and address the many unanswered questions that remain. The intention is that this definition, upon further development, can be used to guide the development of new instruments designed to measure comprehension of informed consent information.

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Laura D. Buccini, M.P.H., is a doctoral candidate at University of Wollongong, School of Health and Behavioral Sciences. This study is one of a series of five studies that she will submit for her final Doctoral thesis. She is currently a Lecturer in Public Health at the University of Wollongong. She has a special interest in the ethics of informed consent in clinical trial research. As first author, she participated in and managed all phases of this study, including design, data synthesis, analysis, and interpretation of study results.

Peter Caputi, Ph.D., is Senior Lecturer in the School of Psychology at the University of Wollongong. His research interests include psychological measurement and statistics. His contribution to this study was predominantly in research design and writing/revising the paper. Peter is a co-supervisor of Laura Buccini's doctoral work in Public Health.

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